REMARKS

Claim Objections

The phrase "and/or" in Claim 44 refers to gp75, not to the combination of gp75, antibodies to gp75, and ligand to c-erbB-2. See, e.g., Page 26, lines 16-20 for a description of "gp75 proteins/polypeptide." Therefore, the suggested correction is not necessary.

Specification

The Abstract is conformance with 37 CFR §1.72. There is no requirement that it be restricted to single paragraph. MPEP 608.01(b) merely states that the abstract is "generally limited to a single paragraph," but does not state that this is a statutory requirement.

§112, second paragraph

The claims, especially when read in light of the specification, would be understood by the skilled worker. For example, methods of screening, diagnosing, monitoring, and prognosticating are described through the specification, e.g., on Pages 13-14, and 26-28. The claim clearly conveys that the recited "detecting and quantitating" and "correlating the detected levels" would be used in the "classifying patients" for the recited purposes. A claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought, as long as the scope of the claim is clear. See, e.g., M.P.E.P. §2173.

Claim 45 adds the recitation that the presence of the recited molecules is detected and quantitated in the human body fluid." Thus, the antecedent basis is proper.

§112, first paragraph

The purpose of the written description requirement is to show that the inventor had possession of the claimed subject matter on the application filing date. The claimed methods are

described throughout the specification, e.g., on Pages 13-14, 26-28, and 91-92. Whether there is a disclosure of a specific ligand is not relevant to the written description issue. In *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998), the applicant had composition claims to a human cDNA coding for human insulin, but failed to disclose its specific DNA sequence as required in *Fiers v. Revel* (984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993)), and other cases. The pending claims do not recite a human cDNA, and are directed to methods, not compositions. The court has repeatedly distinguished between compositions claims, and methods claims. See, e.g., *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995).

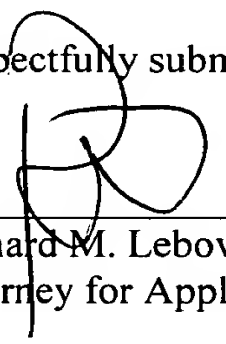
The information contained in the specification is sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. Consequently, the claims are in conformance with §112, first paragraph. Detailed procedures for making and using the invention are unnecessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. See, e.g., M.PE.P. §2164.

The specification is presumptively enabled, and the Patent Office has not provided any reason to doubt the assertions made therein. See, e.g. *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). The specification describes the correlation of c-erbB-2 with cancer (e.g., Pages 6-7; Page 10, line 15; Page 11; Page 13 ("An elevated level of gp75 in a host's body fluid ... is indicative of overexpression of c-erbB-2"); Page 24); tests and assays for gp75 and antibodies thereto; in vivo studies (see, e.g., Examples, Figs. 8-12); and assays for ligands to c-erbB-2 (e.g., Page 34). The specification therefore clearly provides adequate guidance and information at the time the application was filed for the skilled worker to carry out the full scope of the claims. The fact that certain receptor ligands were identified after the application filing date is not by itself relevant; the determinative issue is whether the methods could be carried out without undue experimentation.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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